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élan diagnostics

K021385

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SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC PAK BUN Reagent Kit is intended for the quantitative determination of urea nitrogen in serum, plasma and urine. Urea nitrogen results are used in the diagnosis and treatment of certain renal and metabolic diseases.

The ATAC PAK BUN Reagent determines urea nitrogen through the enzymatic action of urease and glutamate dehydrogenase. The resulting decrease in absorbance at 340 nm is proportional to the urea nitrogen concentration of the sample.

The ATAC PAK BUN Reagent Kit is substantially equivalent to the HiChem BUN Reagent Kit, product no. 88806, which is marketed by Elan Diagnostics Inc. of Brea California.

The effectiveness of ATAC PAK BUN Reagent Kit on the ATAC 8000 Random Access Chemistry System is shown by the following studies.

The recovery of urea nitrogen using the ATAC PAK BUN Reagent is linear from 2 to 100 mg/dL, as shown by the recovery of linearity standards that span the usable range. Regression statistics, which compare standard recoveries to standard values, are shown below.

(ATAC Recoveries) = 0.6 mg/dL + 0.9775 x (Standard Value), $r = 0.9996$, $s_{y.x} = 1.2$ mg/dL, $n = 50$

Precision is demonstrated by the replicate assay of commercially available control serum. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of BUN Recoveries in mg/dL

| | | | Within Run | | Total | |
|---|---|---|---|---|---|---|
| Sample | n | mean | 1SD | %CV | 1SD | %CV |
| Serum 1 | 60 | 7 | 0.3 | 4.4% | 0.4 | 5.6% |
| Serum 2 | 60 | 34 | 0.5 | 1.5% | 0.8 | 2.3% |
| Serum 3 | 60 | 61 | 0.9 | 1.4% | 1.1 | 1.9% |
| Urine 1 | 60 | 21 | 0.4 | 2.1% | 0.5 | 2.5% |
| Urine 2 | 60 | 80 | 1.0 | 1.3% | 1.4 | 1.7% |

Mixed serum, plasma and diluted urine specimens, collected from adult patients, were assayed for urea nitrogen using the ATAC 8000 Random Access Chemistry System and another commercially available method. Results were compared by least squares linear regression and the following statistics were obtained.

Serum/Plasma Comparison

ATAC 8000 = 1.2 mg/dL + 0.977 x Competitive Reagent

$r = 0.996$ $n = 217$ range = 5 - 100 mg/dL

Urine Comparison

ATAC 8000 = 1.9 mg/dL + 0.9525 x Competitive Reagent

$r = 0.991$ $n = 92$ range = 19 - 100 mg/dL



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*is a division of Elan Pharmaceuticals*

The detection limit claim of 2 mg/dL is documented through the repetitive assay of a diluted serum control. The observed standard deviation of a 30 replicate within run precision study was 0 mg/dL. Consequently, the detection limit is reported as twice the round-off error of the assay.

The 14 day on board reagent stability and 14 day calibration stability claims are documented through the assay of serum controls and urine pools over the claimed periods. In all cases, the total imprecision of urea nitrogen recoveries over the test periods are less than 3 mg/dL or 3%.

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 12 2002

Mr. Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics
1075 W. Lambert Road
Brea, CA 92821

Re: k021385
Trade/Device Name: ATAC PAK BUN Reagent
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDQ
Dated: April 29, 2002
Received: May 2, 2002

Dear Mr. Stocking:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021385

Device Name: ATAC PAK BUN Reagent

Indications for Use:

The ATAC PAK BUN Reagent Kit is intended for use with the ATAC 8000 Random Access Chemistry System for the quantitative determination of urea nitrogen in serum, plasma and urine. Urea nitrogen results are used in the diagnosis and treatment of certain renal and metabolic diseases.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

Elan Diagnostics
July 9, 2002

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021385

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)